



COUNTY OF LOS ANGELES

Public Health

JONATHAN E. FIELDING, M.D., M.P.H.
Director and Health Officer

JOHN F. SCHUNHOFF, Ph.D.
Chief Deputy Director

313 North Figueroa Street, Room 909
Los Angeles, California 90012
TEL (213) 240-8117 • FAX (213) 975-1273

www.lapublichealth.org



BOARD OF SUPERVISORS

Gloria Molina
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Yvonne B. Burke
Second District


Zev Yaroslavsky
Third District

Don Knabe
Fourth District

Michael D. Antonovich
Fifth District

October 25, 2007

TO: Each Supervisor

FROM:  Jonathan E. Fielding, M.D., M.P.H.
Director and Health Officer

**SUBJECT: NOTIFICATION OF USE OF DELEGATED AUTHORITY TO ACCEPT
AMENDMENT NUMBER 6 TO GRANT AGREEMENT NUMBER
H18199 WITH THE UNIVERSITY OF SOUTHERN CALIFORNIA FOR
TUBERCULOSIS TRIALS PATIENT STUDIES**

This is to advise you that the Department of Public Health (DPH) will exercise its delegated authority, as approved by the Board of Supervisors on August 29, 2000 (see attached Board letter), to execute Amendment Number 6 to the above-referenced Grant Agreement. Amendment Number 6 increases the grant by \$78,830 from \$547,956 to \$626,786. The budget term for this Agreement is September 23, 1999 through September 22, 2007.

On May 17, 2006, DPH notified the Board that it was exercising its delegated authority and accepted Amendment Number 5, to Grant Agreement Number H18199, which extended the period of performance and increased funding.

On August 16, 2001, December 2, 2003, October 21, 2004, and December 20, 2005, the Department of Health Services notified the Board that it was exercising its delegated authority and accepted Amendments Number 1, 2, 3, and 4 respectively, to Grant Agreement Number H18199, each of which extended the period of performance and increased funding.

County Counsel has reviewed and approved Amendment Number 6 as to form.

If you have any questions or require additional information, please let me know.

JEF:er
DA#00314

Attachment

c: Chief Executive Officer
County Counsel
Executive Officer, Board of Supervisors



→ MARK FINUCANE, Director

COUNTY OF LOS ANGELES
DEPARTMENT OF HEALTH SERVICES
313 N. Figueroa, Los Angeles, CA 90012

(213) 240-8101

BOARD OF SUPERVISORS

Gloria Molina
First District

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Fifth District

August 17, 2000

ADOPTED
BOARD OF SUPERVISORS
COUNTY OF LOS ANGELES

Honorable Board of Supervisors
County of Los Angeles
383 Kenneth Hahn Hall of Administration
500 West Temple Street
Los Angeles, California 90012

88

AUG 29 2000

Violet Varona-Lukens
VIOLET VARONA-LUKENS
EXECUTIVE OFFICER

Dear Supervisors:

TUBERCULOSIS TRIALS CONSORTIUM GRANT AWARD FROM THE UNIVERSITY OF SOUTHERN CALIFORNIA (All Districts) (3 Votes)

IT IS RECOMMENDED THAT YOUR BOARD:

1. Accept a grant award (Exhibit I) from the University of Southern California (USC) in the amount \$96,326, for the provision of active and latent tuberculosis infection patient studies, effective September 23, 1999 through September 22, 2000.
2. Delegate authority to the Director of Health Services or his designee to execute amendments to the USC grant award, accepting future year funding allocations, on behalf of the County of Los Angeles, not to exceed \$1,104,270, effective September 23, 1999 through September 22, 2009.

PURPOSE OF THE RECOMMENDED ACTIONS:

In approving these actions, the Board is:

- accepting a grant award from USC for the Tuberculosis (TB) Trials Consortium project in the amount of \$96,326, effective September 23, 1999 through September 22, 2000.
- authorizing the Director of Health Services, or his designee, to seek and execute amendments to the USC grant award, extending the term through September 22, 2009, with total future year allocations not to exceed \$1,007,944.

JUSTIFICATION:

The Department of Health Services (DHS) is recommending approval of these actions to assist the Federal Centers for Disease Control and Prevention (CDC) in evaluating new tests or approaches for the diagnosis of TB infection and disease.

FISCAL IMPACT:

There are no net County costs. The total program cost of \$96,326 is 100% offset by the USC grant award.

FINANCING:

Funding is included in the Fiscal Year 2000-2001 Adopted County Budget, and will be requested as a continuing appropriation in subsequent fiscal years contingent upon the award of grant funds.

FACTS AND PROVISIONS/LEGAL REQUIREMENTS:

On September 23, 1999, USC entered into an agreement with the CDC for the provision of a TB Trials Consortium. The CDC funded project requires that USC concurrently perform multiple studies and/or clinical trials for the treatment of active TB, for the prevention of active TB in persons with latent TB infection and for the evaluation of new tests or approaches for the diagnosis of TB infection and disease. DHS was identified by USC as one of the TB Trials Consortium project sites.

The USC grant award provides funding support to DHS for the provision of active TB and latent TB patient studies at the Central Public Health Center.

Each treatment protocol implemented locally by the consortium is submitted to the Institutional Review Board for approval at USC and at the CDC.

Attachment A provides additional information.

County Counsel has approved the grant award (Exhibit I) as to form.

CONTRACTING PROCESS:

It is not appropriate to advertise grant awards to the County on the Office of Small Business' Countywide Web Site.

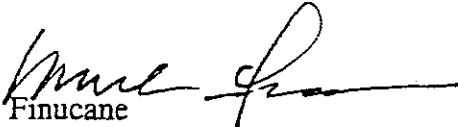
IMPACT ON CURRENT SERVICES (OR PROJECTS):

There is no impact on current DHS services.

Honorable Board of Supervisors
August 17, 2000
Page 3

When approved, this Department requires three signed copies of the Board's action.

Respectfully submitted,


Mark Finucane
Director of Health Services

MF:dhh

Attachments

c: Chief Administrative Officer
County Counsel
Executive Officer, Board of Supervisors

BLETAPH7.DH

SUMMARY OF GRANT AWARD1. TYPE OF SERVICE:

Implementation of a Tuberculosis (TB) Trials Consortium for the provision of active and latent tuberculosis infection patient studies at the Central Public Health Center.

2. AGENCY ADDRESS AND CONTACT PERSON:

University of Southern California
 Division of Infectious Diseases
 1200 North State Street, GNH 6442
 Los Angeles, California 90033
 Attention: Brenda Jones, M.D., Principal Investigator
 Telephone: (323) 343-8288

3. TERM:

Project Term: September 23, 1999 through September 22, 2009
 Budget Term: September 23, 1999 through September 22, 2000

4. FINANCIAL INFORMATION:

Personnel Salaries:	\$ 63,878
Employee Benefits:	16,745
Indirect Costs:	<u>15,703</u>

Total Budget	\$ 96,326
Less: USC Award	<u>96,326</u>
Net County Costs	- 0 -

5. SERVICE INFORMATION:

Estimated study of 50 patients per year, 15 patients with active TB and 35 patients with latent TB infection.

6. GEOGRAPHIC AREA TO BE SERVED:

Countywide.

7. DESIGNATED ACCOUNTABLE FOR PROJECT MONITORING:

Dr. James Haughton, Medical Director, Public Health Programs and Services

8. APPROVALS:

Public Health Programs and Services	Jonathan Fielding, M.D., Director
Contracts and Grants Division:	John H. Ricks, Chief
County Counsel (approval as to form):	Rosemarie Belda, Senior Deputy

SUBCONTRACT

PURCHASE ORDER NO. H18199

PREAMBLE

This is a cost reimbursement Subcontract between the UNIVERSITY of Southern California (hereinafter, "UNIVERSITY") and the Los Angeles County Department of Health Services (hereinafter, "SUBCONTRACTOR") for the delivery of services identified as "Tuberculosis Trials Consortium", defined in Article IA, STATEMENT OF WORK, and in accordance with the terms and conditions set forth herein.

This Subcontract is awarded under the authority of Contract No. 200-1999-00096 issued by the Centers for Disease Control and Prevention.

KEY PERSONNEL

The key personnel representing the UNIVERSITY and the SUBCONTRACTOR shall be as follows:

UNIVERSITY:

Brenda Jones, M.D.
Principal Investigator

SUBCONTRACTOR:

Paul Davidson, M.D.
Key Investigator

In the event a change in Key Investigator is necessary, the UNIVERSITY will be notified within thirty (30) days after the SUBCONTRACTOR reasonably knows the change is necessary.

SUBCONTRACT SCHEDULE

ARTICLE I - PERFORMANCE AND DELIVERY

A. STATEMENT OF WORK - The statement of work to be performed under this Subcontract is described in Exhibit A.

B. PERIOD OF PERFORMANCE - The period of performance of this Subcontract shall be 9/23/99 through 9/22/00.

C. TOTAL ESTIMATED COST - It is estimated that the total cost to the UNIVERSITY for performance of this Subcontract shall not exceed \$96,326.

D. LIMITATION OF FUNDS - The entire work under this Subcontract is contemplated to be performed during the period 9/23/99 through 9/22/00 for a total estimated cost not to exceed \$1,104,270. The amount of \$96,326 presently allotted to this Subcontract is anticipated to cover performance through 9/22/00.

E. DELIVERY - All materials and services called for under this Subcontract shall be completed and delivered to the UNIVERSITY on or before 9/22/00 unless extended by prior written authorization.

F. CLOSE-OUT - No later than sixty (60) days after termination of this Agreement, SUBCONTRACTOR shall submit Exhibit D, Patent Statement and Equipment Report, and Exhibit E, SUBCONTRACTOR's Assignment and Release documents, to the billing address in order to fulfill the reporting requirements of the prime contract.

ARTICLE II - COSTS, PAYMENT, AND BILLING

A. ALLOWABLE COSTS AND FEES - Allowable costs and fees eligible for reimbursement to the SUBCONTRACTOR for performance of this Subcontract shall be determined in accordance with:

1. Applicable Federal Cost Principles as determined by type of organization, including any Amendments in effect on the date of this Subcontract.
2. The budget, attached hereto and incorporated herein as Exhibit B.
3. The terms of this Subcontract.

B. PAYMENT - Payment will be made by the UNIVERSITY to the SUBCONTRACTOR on a quarterly basis, consistent with the provisions of Article IIA, upon presentation of the SUBCONTRACTOR's invoice and subject to availability of funds under Contract No. 200-1999-00096 awarded by the Centers for Disease Control and Prevention. The UNIVERSITY shall not pay any invoice where total payments would result in a cumulative payment in excess of the limitations imposed by Article IIA or where rates used to determine costs vary from those (if shown) in Exhibit B.

The UNIVERSITY, at its option, may elect to pay any invoice in accordance with Article IIA if the invoice is at variance with the article or may return the invoice unpaid to the SUBCONTRACTOR for correction and resubmittal. All payments made are provisional, subject to acceptance (Article IIIA), post-audit, and adjustment.

C. BILLING - Invoices shall be submitted as follows:

1. On a quarterly basis.
2. In triplicate (an original and two copies).
3. Referencing the Subcontract number and numerical sequence of the invoice.
4. Providing detail of expenditure in accordance with the budget categories listed in Exhibit B.
5. A final invoice shall be submitted within sixty (60) days of completion of this

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4. Providing detail of expenditure in accordance with the budget categories listed in Exhibit B.
5. A final invoice shall be submitted within sixty (60) days of completion of this

Certification/Declaration annexed to this Subcontract. Any protocols developed during the course of this Subcontract may not be implemented without specific UNIVERSITY approval and only after review and approval by the NIH Project Officer. Such protocols shall also be subject to the ongoing review of the SUBCONTRACTOR's approved institutional review board and review shall be certified to the UNIVERSITY on an annual basis.

B. CARE AND TREATMENT OF LABORATORY ANIMALS - The SUBCONTRACTOR, if using vertebrate animals under this Subaward shall comply with applicable portions of the Animal Welfare Act (P.L. 89-544, as amended) and shall follow guidelines prescribed in Guide for the Care and Use of Laboratory Animals (NIH Publication No. 85-23, Rev. 1985, or succeeding editions).

C. AUDIT - The books and accounts, files, and other records of the SUBCONTRACTOR which are applicable to this Subcontract at all times shall be available for inspection, review, and audit by the UNIVERSITY and the U.S. Government and its representatives to determine the proper application and use of all funds paid to or for the account or benefit of the SUBCONTRACTOR.

The SUBCONTRACTOR assumes sole responsibility for reimbursement to the agency funding the prime contract a sum of money equivalent to the amount of any expenditures disallowed should the funding agency or an authorized agency rule through audit exception or some other appropriate means, that expenditures from funds allocated to the SUBCONTRACTOR for direct and/or indirect costs were not made in compliance with the applicable cost principles, regulations of the funding agency, or the provisions of this Subcontract.

D. ASSIGNMENT - This Subcontract may not be assigned in whole or in part without the prior written consent of the UNIVERSITY.

E. TERMINATION - This Subcontract may be terminated by either party upon thirty (30) days written notice to the other party, except that the termination of the Prime Contract concurrently terminates this Subcontract with the same date.

F. INDEMNIFICATION - The SUBCONTRACTOR agrees to protect, indemnify and save the UNIVERSITY and the U.S. Government harmless from and against any damage, cost or liability for any and all injuries and/or claims to persons or property arising from acts or omissions of the SUBCONTRACTOR, its employees, agents or subcontractors, howsoever caused.

G. PRIME CONTRACT - All applicable provisions contained in the contract between the UNIVERSITY and the Centers for Disease Control and Prevention, numbered 200-1999-00096, shall be binding upon the SUBCONTRACTOR, and the SUBCONTRACTOR hereby agrees to comply with same. Where appropriate, references to "Government" or "Contracting Officer" shall mean the UNIVERSITY and references to "Contractor" shall mean the SUBCONTRACTOR.

H. BUY AMERICAN - Pursuant to the "Buy American Act" (41 U.S.C. 10), when purchasing equipment or products under this subaward, the SUBCONTRACTOR should, whenever possible, purchase only American-made items.

I. NONDISCRIMINATION - The SUBCONTRACTOR must comply with Title VI of the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973, as amended (Handicapped Individuals) and must have on file with the DHHS Office for Civil Rights valid Assurances of Compliance with the Civil Rights Act of 1964 (Form HHS 441) and Section 504 of the Rehabilitation Act of 1973, as amended (Form HHS 641).

J. EQUAL OPPORTUNITY - The SUBCONTRACTOR is required to file a Standard Form 100, Equal Employment Opportunity Employer Information Report EE01, if the SUBCONTRACTOR has not filed the form within the immediate calendar year. It shall be addressed to: Joint Reporting Committee, c/o EEOC Survey Branch, 2401 East Street, N.W., Washington, D.C. 20506.

K. DISPUTES - Any controversy or claim between the parties arising out of or relating to this Agreement, or a breach thereof, which cannot be resolved by mutual agreement, shall be settled by binding arbitration conducted by a single arbitrator in accordance with the Commercial Arbitration Rules of the American Arbitration Association, and any judgement upon the award rendered by the arbitrator may be entered in any Court having jurisdiction thereof. Any such arbitration shall be held in the County of Los Angeles, California.

L. CERTIFICATIONS AND ASSURANCES

1. Certificate Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion - The SUBCONTRACTOR certifies by signature to this Agreement that it is not suspended, debarred, or otherwise ineligible from entering into funding agreements with any department or other agency of the Federal Government, or in receipt of a notice of proposed debarment or suspension.

The SUBCONTRACTOR shall provide immediate notice to the UNIVERSITY in the event of being suspended, debarred or otherwise declared ineligible by any department or other agency of the Federal Government, or upon notice of a proposed debarment or suspension, either prior to or after execution of this Agreement.

The SUBCONTRACTOR agrees to secure from its Subcontractors or participants in transactions expected to equal or exceed \$25,000, certification that such participants are not suspended, debarred, or otherwise declared ineligible from entering into contracts with any department or agency of the Federal Government, or in receipt of a notice of proposed debarment or suspension.

By signing this Subcontract, the SUBCONTRACTOR has executed and shall abide by the following certifications. If, during the performance period of this Subcontract, the status of the SUBCONTRACTOR changes relative to any of these certifications, it shall immediately notify the UNIVERSITY and include an explanation of the changes.

2. Certification Regarding Lobbying - In the event funds allotted under this Agreement are expected to exceed \$100,000, by signature to this Agreement, SUBCONTRACTOR certifies that it is in compliance with the requirements of Section 1352, Title 31, U.S. Code which

limits the use of appropriated funds to influence certain federal contracting and financial transactions.

3. Drug Free Workplace - By signature to this Agreement, SUBCONTRACTOR certifies that it will comply with the Drug Free Workplace Act of 1988 and its implementing regulations as amended.

4. Misconduct in Science Assurance - The SUBCONTRACTOR hereby gives assurance that an administrative review process has been established regarding procedures for dealing with and reporting possible misconduct in science and reporting requirements of the published scientific misconduct regulations will be followed.

5. Anti-Kickback Act - This Agreement is subject to the terms of the Anti-Kickback Act of 1986 (41 U.S.C. 51-58), which was passed to deter Subcontractors from making payments and contractors from accepting payments for the purpose of improperly obtaining of rewarding favorable treatment in connection with a prime contract or Subcontract relating to a prime contract. The Act imposes criminal penalties in any person who knowingly and willfully engages in the prohibited conduct and provides for the recovery of civil penalties by the United States from any person who knowingly engages in such prohibited conduct and from any person whose employee, Subcontractor, or Subcontractor employee provides, accepts, or charges a kickback.

6. Americans With Disabilities Act - By signature of this Agreement, SUBCONTRACTOR certifies that it complies with the Americans with Disabilities Act of 1990 (42 USC 12101, et. seq.) and all implementing regulations. SUBCONTRACTOR agree to insert the provision of this Article in all subcontracts and purchase orders hereunder.

7. Clear Air and Water - In the event funds allotted under this Agreement are expected to exceed \$100,000, by signature to this Agreement, SUBCONTRACTOR certifies that it is in compliance with all applicable standards, orders or regulations issued pursuant to the Clean Air Act (42 U.S.C. 7401 et seq.) and the Federal Water Pollution Control Act as amended (33 U.S.C. 1251 et seq.). Violations shall be reported to the Federal awarding agency and the Regional Office of the Environmental Protection Agency (EPA).

ARTICLE V - GENERAL TERMS AND CONDITIONS

The General Terms and Conditions are incorporated as Exhibit C of this subcontract.

ARTICLE VI - CONTENTS AND ORDER OF PRECEDENCE

Annexed to this Subcontract are the following exhibits:

- Exhibit A Statement of Work
- Exhibit B Cost Estimate
- Exhibit C General Terms and Conditions
- Exhibit D Patent Statement and Equipment Report

Exhibit E Subcontractor's Assignment and Release

Insofar as these instruments apply to this Subcontract together with the instruments previously enumerated and those listed below, they constitute the entire agreement and understanding between the UNIVERSITY and SUBCONTRACTOR. Moreover, the contents of each instrument below are incorporated within this Subcontract as fully as though set forth herein in their entirety. In the event of a conflict between the provisions of each instrument, the following order of precedence shall govern the rights and obligations of the parties.

1. Subcontract Schedule
2. General Terms and Conditions

ARTICLE VII - ENTIRE AGREEMENT, WAIVERS, AND AMENDMENTS

This Subcontract contains the full and complete agreement between the two parties. All modifications must be in writing and signed by the UNIVERSITY's Contracting Officer and countersigned by the SUBCONTRACTOR's Contracting Officer. No verbal agreements or conversations with any officer or employee of either party shall affect or modify any of the terms and conditions of this Subcontract.

LOS ANGELES COUNTY
DEPARTMENT OF HEALTH SERVICES

Signature



Typed Name John Schunhoff

Title

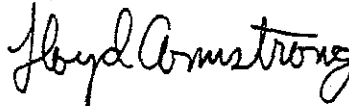
Chief of Staff

Date

Public Health
9/14/00

UNIVERSITY OF SOUTHERN
CALIFORNIA

Signature



Typed Name Lloyd Armstrong, Jr.

Title

Provost and Senior Vice
President for Academic Affairs

Date

6-20-2000

Exhibit A

Statement of Work

We propose a study of 50 patients per year (15 patients with active TB and 35 patients with latent TB infection). USC will initially "partner" with the Central Health Center, which is located 3 miles from the USC Study Site.

The majority of active TB patients will be identified for enrollment at the LAC+USC Medical Center. HIV positive patients will be followed in the HIV Clinic at USC, where Dr. Jones will be the primary care provider. HIV negative patients will be followed at the Central Health Center, where Dr. Alvin Chin will be the primary care provider. The majority of patients with latent TB infection will be identified and followed at the Central Health Center.

Claudia Silva, R.N., is currently the Study Coordinator. In addition to her role as the primary research nurse at USC, Claudia Silva will provide quality assurance for all data collected from USC and TB Control (Central Health Center). She will be in charge of recording and submitting data to the CDC for the enrollment and follow-up of study patients. Claudia Silva will also provide training and assistance to nurses based at the Central Health TB Clinic.

Regular meetings will take place between the staff at USC, TB Control, and the Central Health Center. Dr. Paul Davidson, the Director of TB Control, has been a Co-Investigator and advisor to Dr. Brenda Jones since 1991. Dr. Steve Puentes is the Assistant Medical Director of the LAC+TB Control Program. Dr. Puentes will coordinate efforts to identify and locate potential study participants at the Central Health Center. He will provide clinical consultation to the Central Health Center.

Exhibit B

Cost Estimate

9/23/99 through 9/22/00

Contract No. 200-1999-00096

Key Investigator: Paul Davidson, M.D.

Name	Role on Project	%Effort	Hours	Salary	Fringe	Total
Paul Davidson, M.D.	Co-PI	2	42	\$ -0-	-0-	\$ -0-
Steve Puentes, M.D.	Co-PI	2	42	2,055	539	2,594
Laura Knowles	Epidemiologist	2	42	1,183	310	1,493
Michiko Otaya, RN	Nursing Care Spec.	45	936	25,144	6,591	31,735
Ermelinda Rayos, C.W.	Sr. Comm. Worker	100	2080	35,496	9,305	44,801
Direct Costs				\$63,878	\$16,745	\$80,623
Indirect Costs						15,703
Total Costs						\$96,326

Exhibit C

General Terms and Conditions

L1 52.252-2 Clauses Incorporated by Reference (Feb 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es): <http://www.arnet.gov/far/>

FAR SOURCE	TITLE AND DATE
52.203-3	Gratuities (Apr 1984)
52.203-5	Covenant Against Contingent Fees (Apr 1984)
52.203-6	Restrictions on Subcontractor Sales to the Government (Jul 1995)
52.203-7	Anti-Kickback Procedures (Jul 1995)
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activities (Jan 1997)
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity (Jan 1997)
52.203-12	Limitation on Payment to Influence Certain Federal Transactions (Jun 1997)
52.204-4	Printing/Copying Double-Sided on Recycled Paper (Jun 1996)
52.209-6	Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (Jul 1995)
52.215-2	Audit and Records -- Negotiation (Aug 1996)
52.215-2 Alternate II	(Apr 1998)
52.215-8	Order of Precedence -- Uniform Contract Format (Oct 1997)
52.215-21	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data -- Modifications (Oct 1997)
52.216-7	Allowable Cost and Payment (Apr 1998) This clause is modified by deleting from paragraph (a) the words 'Subpart 31.2' and substituting for them 'Subpart 31.3'.
52.216-11	Cost Contract - No Fee (Apr 1984)
52.216-11 Alternate I	(Apr 1984)
52.216-15	Predetermined Indirect Cost Rates (Apr 1998)
52.219-8	Utilization of Small Business Concerns (Jan 1999)
52.219-9	Small Business Subcontracting Plan (Jan 1999)
52.219-16	Liquidated Damages--Subcontracting Plan (Jan 1999)
52.219-25	Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting (Jan 1999)
52.222-1	Notice to the Government of Labor Disputes (Feb 1997)
52.222-3	Convict Labor (Aug 1996)
52.222-26	Equal Opportunity (Feb 1999)
52.222-35	Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era (Apr 1998)
52.222-36	Affirmative Action for Workers with Disabilities (Jun 1998)
52.222-37	Employment Reports on Disabled Veterans and Veterans of the Vietnam Era (Jan 1999)
52.223-2	Clean Air and Water (Apr 1984)
52.223-6	Drug-Free Workplace (Jan 1997)
52.223-14	Toxic Chemical Release Reporting (Oct 1996)
52.225-11	Restrictions on Certain Foreign Purchases (Aug 1998)
52.227-1	Authorization and Consent (Jul 1995)
52.227-1 Alternate I	(Apr 1984)
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement (Aug 1996)
52.227-14	Rights in Data -- General (Jun 1987)
52.227-14 Alternate IV	(Jun 1987)
52.230-2	Cost Accounting Standards (Apr 1998)
52.230-5	Cost Accounting Standards -- Educational Institution ((Apr 1998)

52.230-6	Administration of Cost Accounting Standards (Apr 1996)
52.232-9	Limitation of Withholding of Payments (Apr 1984)
52.232-17	Interest (Jun 1996)
52.232-20	Limitation of Cost (Apr 1984)
52.232-22	Limitation of Funds (Apr 1984)
	This clause supersedes the Limitation of Cost clause found in the General Provisions of this contract.
52.232-23	Assignment of Claims (Jan 1986)
52.232-25	Prompt Payment (Jun 1997)
52.232-34	Payment by Electronic Funds Transfer - Other than Central Contractor Registration (May 1999)
52.233-1	Disputes (Dec 1998)
52.233-3	Protest After Award (Aug 1996)
52.233-3 Alternate I	(Jun 1985)
52.237-3	Continuity of Services (Jan 1991)
52.242-1	Notice of Intent to Disallow Costs (Apr 1984)
52.242-3	Penalties for Unallowable Costs (Oct 1995)
52.242-4	Certification of Final Indirect Costs (Jan 1997)
52.242-13	Bankruptcy (Jul 1995)
52.243-2	Changes - Cost-Reimbursement (Aug 1987)
52.243-2 Alternate V	(Apr 1984)
52.244-2	Subcontracts (Aug 1998)
52.244-2 Alternate II	(Aug 1998)
52.244-5	Competition in Subcontracting (Dec 1996)
52.244-6	Subcontracts for Commercial Items and Commercial Components (Oct 1998)
52.245-5	Government Property (Cost-Reimbursement, Time-and-Material, or Labor-Hour Contracts) (Jan 1986)
52.245-5 Alternate I	(Jul 1985)
52.249-5	Termination for Convenience of the Government (Educational and Other Nonprofit Institutions) (Sep 1996)
52.251-1	Government Supply Sources (Apr 1984)
52.253-1	Computer Generated Forms (Jan 1991)

HHSAR SOURCE	TITLE AND DATE
352.202-1	Definitions (Apr 1984)
352.202-1 Alternate I	(Apr 1984)
352.228-7	Insurance - Liability to Third Persons (Dec 1991)
352.232-9	Withholding of Contract Payment (Apr 1984)
352.233-70	Litigation and Claims (Apr 1984)
352.242-71	Final Decisions on Audit Findings (Apr 1984)
352.270-7	Paperwork Reduction Act (Apr 1984)

Additional Clauses:

FAR SOURCE	TITLE AND DATE
52.246-8	Inspection of Research and Development - Cost Reimbursement (Apr 1984)
52.246-8 Alternate I	(Apr 1984)
52.242-15	Stop-Work Order (Aug 1989)
52-242-15 Alternate I	(Apr 1984)

Exhibit D

UNIVERSITY of Southern California
Department of Contracts and Grants

Subcontract No. _____

Reporting Period _____

Principal Investigator _____

INVENTION STATEMENT

Any invention was ___ was not ___ conceived or first actually reduced to practice in the performance of work during the Subcontract reporting period.

EQUIPMENT REPORT

Equipment was ___ was not ___ purchased during the Subcontract reporting period. If equipment was purchased during the Subcontract period, please provide the following information:

Description of the equipment item
Manufacturer, model number, and serial number
Cost charged to the Subcontract
Acquisition date

Signature of Principal Investigator

Date

Signature of Authorizing Official

Date

Exhibit E

SUBCONTRACTOR'S ASSIGNMENT OF REFUNDS, REBATES, AND CREDITS

Pursuant to the terms of Subcontract Number _____ under prime Grant/Contract Number _____ and in consideration of the reimbursement of costs and payment of fee, as provided in the said Subcontract and any assignment thereunder, the _____ (hereinafter called the SUBCONTRACTOR) does hereby

1. Assign, transfer, set over and release to the UNIVERSITY OF SOUTHERN CALIFORNIA (hereinafter called the UNIVERSITY) all rights, title and interest to all refunds, rebates, credits other amounts (including any interest thereon) arising out of the performance of the said Subcontract, together with all rights of action accrued or which may hereafter accrue thereunder.

2. Agree to take whatever action may be necessary to effect prompt collection of all refunds, rebates, credits or other amounts (including any interest thereon) due or which may become due and to promptly forward to the UNIVERSITY check made payable to the UNIVERSITY OF SOUTHERN CALIFORNIA for any proceeds so collected. The reasonable costs of any such action to effect collection shall constitute allowable costs when approved by the UNIVERSITY as stated in the said Subcontract and may be applied to reduce any amounts otherwise payable to the UNIVERSITY under the terms hereof.

3. Agree to cooperate fully with the UNIVERSITY as to any claim or suit in connection with refunds, rebates, credits or other amounts due (including any interest thereon); to execute any protest, pleading, application, power of attorney or other papers in connection therewith; and to permit the UNIVERSITY to present it at any hearing, trial or other proceeding arising out of such claim or suit.

IN WITNESS WHEREOF this assignment has been executed this _____ day of _____, 19 ____.

SUBCONTRACTOR:

By:

(Name of Authorized Official)

Title:

CERTIFICATE (To be completed by an officer other than the one certifying above)

I _____ certify that I am _____
(Name) (Title)

_____ of the of the corporation named as SUBCONTRACTOR in the foregoing

assignment, that _____ who signed said assignment on behalf of the

SUBCONTRACTOR was then _____
(Name of Authorized Official)

_____ of said corporation; that said
(Official Title)

assignment was duly signed from and on behalf of said corporation by authority of its governing body and is within the scope of its corporate powers.

(Name and Title of Official Certifying this form)

SUBCONTRACTOR'S RELEASE

Pursuant to the terms of Subcontract Number _____ under prime Grant/Contract Number _____

_____ for the period _____ through _____ and in
(Beginning Date) (Expiration Date)

consideration of the sum of _____ which has been paid under
(Cumulative expenses claimed/to be claimed)

Subcontract to _____ (hereinafter called the SUBCONTRACTOR) or to its
(SUBCONTRACTOR's Name)

assignees, if any, the SUBCONTRACTOR, upon payment of the said sum by the UNIVERSITY OF SOUTHERN
CALIFORNIA, Los Angeles, California 90089 (hereinafter called UNIVERSITY) does remise, release, and
discharge the UNIVERSITY, its officers, agents, and employees, of and from all liabilities, obligations, claims
and demands whatsoever under or arising from the said Subcontract.

IN WITNESS WHEREOF, this release has been executed this _____ day of _____ 19__.

(SUBCONTRACTOR)

By

(Name of Authorized Official)

Title

Certificate (To be completed by an officer other than the one certifying above)

I _____ certify that I am _____ of the corporation named
(Name of Official) (Official Title)
as SUBCONTRACTOR in the foregoing release, that _____ who signed said release
(Official certifying above)
on behalf of the SUBCONTRACTOR was then _____ of said corporation; that
(Official Title)
said release was duly signed from and on behalf of said corporation by authority of its governing body and is within the
scope of its corporate powers.

Protection of Human Subjects
Assurance Identification/Certification/Declaration
(Common Federal Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the common rule. See section 101(b) the common rule for exemptions. Institutions submitting applications or proposals for support must submit certification or appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the common rule.

Institutions with an assurance of compliance that covers the research to be conducted on file with the Department, Agency, or the Department of Health and Human Services (HHS) should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency. Institutions which do not have such an assurance must submit an assurance and certification of IRB review and approval within 30 days of a written request from the Department or Agency.

1. Request Type <input type="checkbox"/> ORIGINAL <input type="checkbox"/> FOLLOWUP <input type="checkbox"/> EXEMPTION	2. Type of Mechanism <input type="checkbox"/> GRANT <input type="checkbox"/> CONTRACT <input type="checkbox"/> FELLOWSHIP <input type="checkbox"/> COOPERATIVE AGREEMENT <input type="checkbox"/> OTHER: _____	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
4. Title of Application or Activity		5. Name of Principal Investigator, Program Director, Fellow, or Other

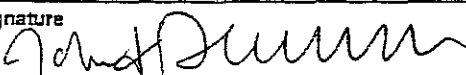
6. Assurance Status of this Project (Respond to one of the following)

- ☐ This Assurance, on file with Department of Health and Human Services, covers this activity;
Assurance identification no. M-_____ IRB identification no. _____
- ☐ This Assurance, on file with (agency/dept) _____, covers this activity.
Assurance identification no. _____ IRB identification no. _____ (if applicable)
- ☐ No assurance has been filed for this project. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.
- ☐ Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph _____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

- ☐ This activity has been reviewed and approved by the IRB in accordance with the common rule and any other governing regulations or subparts on
(date) _____ by: ☐ Full IRB Review or ☐ Expedited Review
- ☐ This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the common rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed and certification will be provided.		10. Name and Address of Institution Department of Health Services 313 North Figueroa Street Los Angeles, California 90013	
11. Phone No. (with area code) (213) 240-8156	12. Fax No. (with area code) (213) 481-2739		
13. Name of Official John Schunhoff, Ph.D		14. Title Chief of Staff, Public Health	
15. Signature 		16. Date 09/14/00	